

Appl. No. 10/030,735
Amdt. dated February 10, 2006
Amendment and Reply under 37 CFR 1.116 Expedited
Procedure Examining Group 1644

PATENT

REMARKS/ARGUMENTS

The following is relative to the "final" Office Action mailed July 12, 2005.

Page 16 of the Specification has been restored to the text as originally filed in light of helpful suggestions from Quality Assurance Specialist (QAS) Bonnie Eyler as described further below. Briefly, the text presents Formula (I) followed by the detailed and precise description of positions in the formula in Markush type language as originally presented.

Claims 1, 2, 5, 8, 9, and 46 have been revised to utilize the same formula I as found on page 16 of the specification and in the claims as originally filed. The formula is followed by the same type of detailed and precise description of the positions in the formula in the same Markush type language as found on page 16. More specifically, and in claim 1, position X_1 is selected from the group consisting of N, Q, and D; position X_2 is V; position X_3 is R; and position X_4 is L. The previous possibility of position X_1 as F has been moved to claim 5 (which previously depended from claim 1) so that claim 5 now contains all other features of previous claim 1. No other feature of claim 1 has been changed except as discussed below. The scope of claim 1 with respect to positions X_1 through X_4 as previously presented is now identically found in a combination of claims 1 and 5. No loss of claim scope was intended or believed to have occurred.

Claims 1 and 46 have also been revised to no longer be directed to "partial" retro-inverso sequences. A corresponding cancellation of claim 7 is also made. These changes are not made in acquiescence to any position set forth in the Office Action mailed July 12, 2005 but rather to reduce the number of issues remaining in the instant application. Applicants expressly reserve the right to pursue the "partial" retro-inverso subject matter in a continuing application.

Relative to the previous response filed November 11, 2005 and the Advisory Action mailed December 29, 2005, Applicants respectfully point out that the term "optionally" is not present in revised claim 5 and there is no inadvertent duplication of claim 10.

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No new matter has been introduced, and entry of the above revisions to the specification and claims is respectfully requested.

Advisory Action Mailed December 29, 2005

Applicants appreciate the helpful indications and comments in the Advisory Action mailed December 29, 2005. As noted in the Advisory Action, entry of the above revised claims would render at least claims 4, 10, and 46-54 allowed. Also, Applicants have addressed the informalities with respect to claim 5 and the inadvertent duplication of claim 10.

Applicants also believe that the additional comments in the Advisory Action indicate that the only remaining "new matter" issue in claims 1-3, 8, 9, 13, and 14 is that of peptide position X₄ as a Leucine residue. This issue is addressed below.

Applicants respectfully point out that claim 5 is an independent claim that features peptide position X₄ as Phenylalanine. Thus Applicants believe that claim 5 is not subject to the "new matter" issue identified in the Advisory Action.

Withdrawn Claims and Rejoinder

Claims 20, 21, 23-26, and 28-30 were withdrawn from consideration. Claims 20, 21, 23-26, and 28-30 remain directed to methods comprising the use of a peptide according to claim 1 (claims 20, 21, 23-26, and 28-29) or claim 2 (claim 30). As such, they have all the limitations of elected claims 1 and 2 and are subject to rejoinder as set forth at MPEP 821.04. Applicants respectfully ask that claims 20, 21, 23-26, and 28-30 be rejoined and allowed along with claims 1 and 2.

Furthermore, Applicants thank the Examiner for suggesting the use of dual status identifiers. As the claims are not further revised above, the single status "withdrawn" identifier has been used for claims 20, 21, 23-26, and 28-30.

Apparent "New Matter" Issue under 35 U.S.C. § 112, first paragraph

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As noted above, the Advisory Action appears to raise a "new matter" issue with respect to Claims 1-3, 8, 9, 13 and 14, presumably under 35 U.S.C. § 112, first paragraph. The Advisory Action statement alleges that the claim feature of peptide position X₄ as a Leucine residue is "new matter" because "the specification does not specifically contemplate limiting to that single amino acid and the specification lacks of representative species of that specific amino acid explicitly disclosed and there was no indication that L4 was equivalent to F4."

Applicants have carefully reviewed the Advisory Action statement and respectfully, but emphatically, maintain the position that no *prima facie* case of "new matter" is present against the above revised claims.

The position reflected in the above quote from the Advisory Action statement appears to require that the specification:

- 1) "specifically contemplate" peptide position X₄ as a Leucine residue; and/or
- 2) "explicitly disclose" representative species of peptides with position X₄ as a Leucine residue; and/or
- 3) "indicate" that Leucine at peptide position X₄ is equivalent to Phenylalanine at the same position.

While no specific basis is provided in the Advisory Action for why the above three requirements are to be met, Applicants respectfully submit that the position reflected above is factually misplaced.

Applicants respectfully point out that as clearly evident from the application and claims as originally filed, peptide position X₄ is clearly identified as being "selected from the group consisting of V, I, L and F" (see, for example, claim 1 as originally filed). Therefore, and contrary to the above quote, there was "specific contemplation" of peptide position X₄ as possibly being a Leucine residue, along with the position possibly being a Valine, an Isoleucine, or a Phenylalanine residue. This "contemplation" also reflects how these four amino acid possibilities for peptide position X₄ were viewed as being equivalent and so interchangeable in

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the operation of the claimed invention. The statement in the Advisory Action fails to recognize these point and so appears misplaced at least with respect to items 1) and 3) above.

As for item 2) above, a requirement for "representative species" to be "explicitly disclosed" appears to be a requirement for an actual reduction to practice. If a constructive reduction to practice was sufficient, as permitted under U.S. patent law, then the recitation of peptide position X₄ as being "selected from the group consisting of V, I, L and F" in the application as originally filed would already be sufficient.

Applicants point out, however, that establishment of a *prima facie* case of an inadequate written description under 35 U.S.C. § 112, first paragraph, cannot be, in effect, a requirement for an "actual reduction to practice" of the claimed invention. The Federal Circuit has stated that an actual reduction to practice is not needed to provide an adequate written description of a claimed invention. The Court in *University of Rochester*¹ stated that

"[w]e of course do not mean to suggest that the written description requirement can be satisfied only by providing a description of an actual reduction to practice. Constructive reduction to practice is an established method of disclosure...."

Thus actual reduction to practice is not required. Constructive reduction to practice is sufficient.

In light of the above, Applicants respectfully submit that there is no *prima facie* issue of "new matter" with respect to the claim feature of peptide position X₄ as being a Leucine residue, and claims 1-3, 8, 9, 13, and 14 may be indicated as allowable.

In the event that this issue is maintained, Applicants respectfully point out that the issue of an adequate description of peptide position X₄ as a Leucine residue was not previously presented as a specific issue during prosecution. To the contrary, the search and examination of the instant application specifically included application of references with peptides containing

¹ *University of Rochester v. G.D. Searle & Co.*, 69 USPQ2d 1886 (Fed. Cir. 2004). See also *Gould v. Quigg*, 822 F.2d 1074, 1078, 3 USPQ2d 1302, 1304 (Fed. Cir. 1987).

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corresponding X₄ positions that were Leucine residues (see the Office Action mailed May 21, 2004, for example). Thus the issue appears to have been raised for the first time in the Advisory Action, which precludes it from being an adequate basis for maintaining finality of the last Office Action (mailed July 12, 2005). Therefore, and should this issue be maintained, Applicants respectfully request the re-opening of prosecution, via a non-final Office Action, so that the issue may be adequately addressed.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 858-350-6151.

Respectfully submitted,


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